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Fresenius PD+ *IQcard*™ Cycler
510(k) Premarket Notification

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name:	Fresenius Medical Care North America
Address:	95 Hayden Ave Two Ledgemont Center Lexington, MA 02420
Phone:	1-781-402-9068
Fax:	(781) 402-9082
Contact Person:	Arthur Eilinsfeld, Director of Regulatory Affairs
Date of Preparation:	9 January, 2001

B. Device Name:

Trade Name:	Fresenius PD+ *IQcard*™ Cycler
Common/Usual Name:	Peritoneal Dialysis Cycler
Classification Name:	System, Peritoneal, Automatic Delivery

C. Predicate Device Name:

The predicate devices for the Fresenius PD+ *IQcard*™ Cycler are the following:

- Fresenius PD+ Cycler - #K915634 (7/1/93);
- Inpersol 3000 - #K895336 (11/28/89);
- Fresenius 90/2 Cycler - #K902149 (10/30/90);
- Baxter HomeChoice Pro – 510(k) number unknown, commercially available.

Summary of Safety and Effectiveness

D. Device Description/Indications for Use:

The intended use for the PD+ *IQcard*™ Cycler is similar to that for the Fresenius PD+ Cycler and is as follows:

Intended Use for PD+ Cycler

The Fresenius PD+ Cycler is indicated for acute and chronic peritoneal dialysis.

Intended Use for PD+ IQcard™ Cycler

The Fresenius PD+ IQcard™ Cycler is indicated for acute and chronic peritoneal dialysis. The following therapies are supported: continuous cycling peritoneal dialysis (CCPD), intermittent peritoneal dialysis (IPD), tidal peritoneal dialysis (TPD), and PD Plus peritoneal dialysis (CCPD + daytime exchange delivered from the cycler).

E. Substantial Equivalence:

510(k) Substantial Equivalence Decision Making Process

1. **Is the product a device?**

   YES - The Fresenius PD+ *IQcard*™ Cycler is a device pursuant to 21 CFR §201 [321] (h).

2. **Does the new device have the same intended use?**

   YES – The intended use for the PD+ *IQcard*™ Cycler is similar to that for the Fresenius PD+ Cycler and is as follows:

   Intended Use for PD+ Cycler

   The Fresenius PD+ Cycler is indicated for acute and chronic peritoneal dialysis.

   Intended Use for PD+ IQcard™ Cycler

   The Fresenius PD+ IQcard™ Cycler is indicated for acute and chronic peritoneal dialysis. The following therapies are supported: continuous cycling peritoneal dialysis (CCPD), intermittent peritoneal dialysis (IPD), tidal peritoneal dialysis (TPD), and PD Plus peritoneal dialysis (CCPD + daytime exchange delivered from the cycler).

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3. **Does the device have technological characteristics that raise new types of safety or effectiveness questions?**

   NO – The PD+ *IQcard*™ Cycler is an updated version of the Fresenius PD+ Cycler that incorporates features found on other Fresenius cyclers. In addition, the PD+ *IQcard*™ Cycler includes a feature, which allows for the downloading of patient compliance information from the cycler and the uploading of treatment parameters to the cycler. The features included in the PD+ *IQcard*™ Cycler are equivalent to those present on commercially available peritoneal dialysis cyclers and raise no new types of safety or effectiveness questions. Table III-1 provides a comparison of the features of the PD+ *IQcard*™ Cycler, Fresenius PD+ Cycler and other commercially available PD cyclers.

4. **Does descriptive or performance information demonstrate equivalence?**

   YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the PD+ *IQcard*™ Cycler and demonstrates that it is substantially equivalent to other commercially available cyclers.

F. Safety Summary

The Fresenius PD+ *IQcard*™ Cycler Functional and Software validation and release testing rigorously tested the features of the PD+ *IQcard*™ Cycler. The results of this testing indicate that the Fresenius PD+ *IQcard*™ Cycler is safe and effective for its intended use.

G. General Safety and Effectiveness Concerns

The device labeling contains an Operator's Manual, which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the device. In addition, extensive training is provided to patients that use the Fresenius PD+ *IQcard*™ Cycler. This information promotes safe and effective use of the device.

Arthur Eilinsfeld
Director of Regulatory Affairs

1/10/01
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2001

Ms. Nichole Riek
Regulatory Affairs Specialist
Fresenius Medical Care North America
95 Hayden Avenue
LEXINGTON MA 02420

Re: K002892
Fresenius PD+ *IQcard*™ Cycler
Dated: January 12, 2001
Received: January 16, 2001
Regulatory Class: II
21 CFR §876.5630/Procode: 78 FKX

Dear Ms. Riek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Fresenius Medical Care

Indications for Use Statement

Device Name:

Fresenius PD+ *IQcard*™ Cycler

Indications for Use:

The Fresenius PD+ IQcard™ Cycler is indicated for acute and chronic peritoneal dialysis. The following therapies are supported: continuous cycling peritoneal dialysis (CCPD), intermittent peritoneal dialysis (IPD), tidal peritoneal dialysis (TPD), and PD Plus peritoneal dialysis (CCPD + daytime exchange delivered from the cycler).

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002892

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)